

Document Retention in EU Competition Cases

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On 25 March 2021, the Court of Justice of the EU (“CJEU”) confirmed the fines imposed in Europe on a number of pharmaceutical companies, including Xellia and Alpharma, for entering into anticompetitive ‘pay for delay’ settlement agreements.

One of the grounds of appeal rejected by the CJEU concerned the impact of the lengthy administrative procedure on Xellia’s and Alpharma’s rights of defence. The CJEU found that Xellia and Alpharma had not proven that the Commission’s investigatory steps had taken so long as to impact their rights of defence. In particular, Xellia and Alpharma could not blame the Commission for their own failure to preserve documents that could have assisted their defence.

The CJEU’s judgment sends a message to companies active in sectors under investigation. Although there is no general obligation to preserve documents which would assist the Commission in the exercise of its investigatory powers in competition cases, companies are advised to preserve key documents and legal assessments for the purposes of their own defence – even when the investigation appears unconscionably dilatory. Once aware of being a possible target of a Commission investigation, companies should preserve all relevant documents until they can be confident that no further action will be taken. Given the recent practice of the Commission to make infringement findings against companies even where fines cannot be imposed for prescription reasons, that period of time may be very long indeed.

I. Background

In 2002, Lundbeck entered into settlement agreements with a number of generic pharmaceuticals manufacturers and resellers, including Alpharma. The settlement agreement between Lundbeck and Alpharma was in effect until 30 June 2003. For the period of the agreement, Alpharma generally committed not to sell generic citalopram in the EU, Norway and Switzerland, in exchange for payments from Lundbeck amounting US\$ 12 million.

In October 2003, the Danish Competition Authority informed the Commission of the settlement agreements entered into by Lundbeck and the generics manufacturers and resellers. In a press release issued on 28 January 2004, the Danish Competition Authority indicated that “*the Commission [did] not wish to initiate proceedings against Lundbeck.*”^[1] However, unbeknown to the public, between 2003 and 2006 the Commission conducted inspections (so-called ‘dawn raids’), primarily at Lundbeck’s premises in Europe.

In 2008 and 2009, the Commission conducted a formal inquiry into the pharmaceutical sector. The Final Report of the Commission on the Pharmaceutical Sector Inquiry examined competition issues relevant to Lundbeck as well as Alpharma and Xellia, such as patent filing strategies (including related exchanges and litigation), as well as settlements and other related agreements.^[2]

Some eight years after the Lundbeck settlement agreements, the Commission opened investigations into Lundbeck in 2010 and into Alpharma and Xellia in March 2010 and March 2011, respectively. The Commission adopted an infringement decision in June 2013 imposing fines of approximately €146 million for ‘pay for delay’ anti-competitive agreements entered into by Lundbeck, Alpharma, Xellia and other generic manufacturers and resellers.

On appeal before the General Court and the CJEU, Xellia and Alpharma argued that the Commission had infringed their rights of defence by failing to inform them in a timely manner of the existence of an inquiry concerning them, which allegedly caused them not to retain potentially exculpatory evidence. In particular, Xellia and Alpharma referred to three categories of documents that had been lost due to the lapse of time: (i) drafts and comments relating to the agreements at issue, (ii) the business plans of Alpharma relating to citalopram, and (iii) the documents of external counsel.

At first instance, the General Court ruled that Xellia and Alpharma were under a duty of diligence, applicable to all investigated parties in EU antitrust proceedings, to retain all relevant documentation and evidence in order to safeguard their rights of defence.^[3]

According to the General Court, the duty of diligence arose in this case due to the press release of the Danish Competition Authority of 28 January 2004, and the Commission's Pharmaceutical Sector Inquiry of 2008-2009.^[4]

The CJEU disagreed with the General Court's reasoning. It clarified that the duty of diligence exists but only applies to investigated companies once formal proceedings have been opened against them. In the cases of Xellia and Alpharma, the duty did therefore not arise until 2010 and 2011, when the Commission formally opened investigations against them. Somewhat inconsistently, the CJEU indicated that a "duty of care" should have led Xellia and Alpharma to preserve all relevant documentation as of the date of the opening of the Pharmaceutical Sector Inquiry, some four and a half years after the settlement agreements had expired.^[5]

II. Obligation to Preserve Documents in EU Competition Cases

Document retention rules in Europe are generally covered by national legislation. With regard to commercial negotiations and other business arrangements, companies are generally required under national law to preserve company books and records for a precautionary period of time (e.g., five years).

EU competition law does not impose any general obligation on companies to preserve documents that are or could be relevant to an antitrust investigation. However, EU case law has established a general "duty of care" concerning companies and trade associations, to ensure the proper maintenance of information about their activities for evidentiary purposes.^[6] Furthermore, when companies receive requests for information from the Commission, they are expected to act with greater diligence and to take all appropriate measures in order to preserve such evidence as might be reasonably available.^[7]

Once an investigation is underway, companies have a general duty to cooperate in response to Commission requests for information and inspections. In particular, the Commission has powers to request correct, accurate and complete information and documentation.^[8] Companies are also obliged to produce complete company books and records during dawn raids, and the duty of cooperation is increased when inspections have been authorised by decision.^[9]

III. Deferred Detection and Lengthy Proceedings Do Not Excuse Document Losses or Short Retention Policies

General principles of EU law dictate that administrative procedures relating to competition policy must be conducted within a reasonable time. EU Courts apply this principle by analysing the impact of lengthy investigations on the rights of defence of companies, and can reduce the amount of fines imposed where appropriate.^[10]

The Commission's failure to observe the duty to deal with a matter within a reasonable period of time normally has no effect on the validity of the administrative procedure under Regulation No. 1/2003.^[11] Limited exceptions to this general rule may be found in EU case law, for example, when the Commission fails to investigate a company for five consecutive years, thereby exceeding the statute of limitations set in Regulation No. 1/2003.^[12] In order to argue successfully that their rights of defence have been infringed through the dilatoriness of the Commission's investigation, companies must prove that they acted diligently during the different phases of an investigation and that specific and avoidable harm was caused to them.^[13]

In the Alpharma and Xellia cases, the General Court considered that the Commission had carried out a number of relevant investigative steps in the period between the receipt by the Commission of the Lundbeck settlement agreements (October 2003) and the initiation of proceedings against Alpharma and Xellia (2010 and 2011, respectively). Furthermore, the press release of the Danish Competition Authority of 28 January 2004 demonstrated that the Commission was taking an interest in Lundbeck's settlement agreements. Xellia and Alpharma ought to have been aware of the Commission's likelihood of investigating 'pay for delay' agreements in the pharmaceutical sector, and should have acted with greater diligence to preserve any information that could be relevant for the investigation.^[14]

The CJEU ultimately disagreed with the General Court on this point, considering that the "duty of diligence" did not apply during the pre-investigation phases (i.e., from 2003 to 2010-2011 in the case of Xellia and Alpharma).^[15] However, the application of the general principle of the "duty of care", coupled with the relatively short period between the expiration of the Lundbeck settlement agreements and the Pharmaceutical Sector Inquiry (four and a half years), led the CJEU to the same conclusion as the General Court: Xellia and Alpharma could not blame the Commission for their respective failures to retain relevant evidence:

"a specific duty of care requiring [companies] to ensure that information enabling details of their activities to be retrieved is retained properly in their books or records, in order, in particular, that they have in their possession the necessary evidence in the event of subsequent administrative action or judicial proceedings. [...] [A] well-informed and seasoned operator [...] could not be unaware and [...] take precautions against the loss, due to the passage of time, of evidence that might prove to be useful

to them in the context of subsequent administrative procedures or judicial proceedings.”^[16]

IV. Conclusion

Although EU legislation does not contain a formal duty to preserve documents that the Commission may seek or require to be produced during the course of an investigation, a failure to preserve information may weaken a firm’s ability to defend itself in subsequent proceedings. In particular, the possibility of deferred enforcement or lengthy Commission investigations does not negate the fact that it is in the firm’s own interest to preserve relevant documents for the purposes of subsequent litigation.

Whilst this has always been recognised with respect to civil claims, it is now clear that firms would be well-advised to preserve potentially exculpatory materials, especially if they became aware that practices similar to those that they are engaging in have become the subject of an EU antitrust investigation. This includes both cases against individuals firms and sector inquiries.

In practice, as a first step, such firms and their legal advisors should ensure that they have arranged appropriate document retention policies and practices for their emails, other internal documents and communications with actual or potential competitors. As a second step, it is important to monitor legal developments affecting the sectors in which they operate, and to be aware of the different retention obligations they may face in different jurisdictions. Finally, in taking these protective measures, companies should take into account the limited scope of legal professional privilege in EU competition cases, and to ensure that protected documents are clearly labelled as such and filed separately.

[1] See Case AT.39226 – *Lundbeck*, para. 728.

[2] See Pharmaceutical Sector Inquiry, Final Report, 8 July 2009, Section C.2.

[3] See Case T-471/13 *Xellia and Alpharma v Commission*, EU:T:2016:460, paras. 353 ff.

[4] See Case T-471/13 *Xellia and Alpharma v Commission*, EU:T:2016:460, para. 368.

[5] See Case C-611/16 P *Xellia and Alpharma v Commission*, EU:C:2021:245, paras. 135 ff.

[6] See Case T-240/07 *Heineken v Commission*, EU:T:2011:284, para. 301.

[7] See Case T-5 and 6/00 *Neederlandse Federatieve Vereniging voor de Groothandel op Elektrotechnisch Gebied and Technische Unie v Commission*, EU:T:2003:342, para. 87.

[8] See Regulation No 1/2003, Article 23(1).

[9] See Regulation No 1/2003, Article 23(1)(c). Most inspections are authorised by formal Decision of the Commission. *Per contra*, most requests for information sent by the Commission are not made pursuant to a formal Decision (and in that sense responding may be considered to be a voluntary act).

[10] See Case C-445/11 P *Bavaria v Commission*, EU:C:2012:828, para. 77.

[11] See Case T-410/03 *Hoechst v Commission*, EU:T:2008:211, para. 227.

[12] See Case T-213/00 *CMA CGM et al. v Commission*, EU:T:2003:76, para. 482.

[13] See C 201/09 P and C 216/09 P *ArcelorMittal Luxembourg et al. v Commission*, EU:C:2011:190, para. 118; Case T-240/07 *Heineken Nederland and Heineken v Commission*, EU:T:2011:284, para. 300 ff; Case T-410/03 *Hoechst v Commission*, EU:T:2008:211, para. 227.; and Case T-471/13 *Xellia and Alpharma v Commission*, EU:T:2016:460, paras. 357 and 358.

[14] See Case T-471/13 *Xellia and Alpharma v Commission*, EU:T:2016:460, paras. 353 ff.

[15] See Case C-611/16 P *Xellia and Alpharma v Commission*, EU:C:2021:245, paras.127-148.

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[16] See Case C-611/16 P *Xellia and Alpharma v Commission*, EU:C:2021:245, paras.151-152.

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